



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/054,796 | 01/23/2002 | Emmanuel C. Opara | 5405.223IPDV | 4935 |

20792 7590 07/01/2003

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER

NAFF, DAVID M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 07/01/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|-----------|----------------|-------|
| Application No. | 10/054796 | Applicant(s) | Opera |
| Examiner | Maft | Group/Art Unit | 1051 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 1/23/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

Claim(s) 6-13, 77 + 84 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 6-13, 77 + 84 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 *Filed 1/23/02* Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

The preliminary amendment of 3/23/02 amended the specification, canceled claims 1-5, 14-76 and 78-83, amended claims 6-13 and 77, and added new claim 84.

Claims examined on the merits are 6-13, 77 and 84 which are all 5 claims in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 Claims 6-13, 77 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brothers (5,821,121) (249 on 1449) in view of Brockbank (5,071,741) (50 on 1449) or Hamaguchi et al (272 on 1449) or Garfinkel et al (266 on 1449) each taken with Janjic et al (274 on 1449) or Littman et al (269 on 1449) or Garfindel et al (265 on 1449).

20 The claims are drawn to a microencapsulated islet cell product containing microcapsules containing pancreatic islet cells wherein the cells exhibit a weight gain of not more than 10 percent over a period of one month in a physiological saline solution at 37 degrees Celsius and exhibiting at least 150 percent basal insulin secretion in response to 25 16.7 millimolar glucose challenge in Krebs-Ringer physiological solution at pH 7.4 after the period of one month.

Brothers discloses culturing pancreatic islet cells in a medium containing glutathione (antioxidant) (col 42, line 16; col 49, line 45;

and col 51, line 12). The cultured cells may be encapsulated for implanting (col 18, lines 31-41).

Brockbank, Hamaguchi et al and Garfinkel et al (document 266) disclose microencapsulation of pancreatic islets for transplantation.

5 Janjic et al, Littman et al and Garfinkel et al (document 265) disclose enhancing insulin secretion of pancreatic islets by treating the islets with glutathione which functions as an antioxidant.

It would have been obvious to carry out the encapsulation of pancreatic islet cells as suggested by Brothers by microencapsulating the 10 cells to obtain the function of microencapsulating the pancreatic islets for transplantation as taught by Brockbank, Hamaguchi et al or Garfinkel et al (document 266) when microencapsulating pancreatic islets for transplantation. Janjic et al, Littman et al or Garfinkel et al (document 265) would have suggested that glutathione in the medium of 15 Brothers will function to enhance insulin secretion by the pancreatic islets. The resulting cultured microencapsulated cells would have inherently had a weight gain and basal insulin secretion as presently claimed.

20 *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible 25 harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

30 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting

application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the 5 assignee must fully comply with 37 CFR 3.73(b).

Claims 6-13, 77 and 84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,303,355 B1. Although the conflicting claims are not identical, they are not patentably distinct from each 10 other because it would have been obvious to produce the presently claimed microencapsulated cells as disclosed by the copending application claims by culturing pancreatic islet cells in a medium containing an antioxidant, cryopreserving the cells in a medium containing at least one of an antioxidant, anti-cytokine, anti-endotoxin or antibiotic, and 15 microencapsulating the cells. The resultant microencapsulated cells would have inherently had a weight gain and basal insulin secretion as presently claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone 20 number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

25 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist
5 whose telephone number is (703) 308-0196.

10 DMN
6/30/03


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651